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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------------------|----------------------|---------------------|------------------|
| 10/057,352 | 01/24/2002 | Hien Vu Nguyen | PPC-823 | 2014 |
| 27777 PHILIP S. JOH | 7590 12/21/200 NSON | EXAMINER | | |
| JOHNSON & JOHNSON | | | REICHLE, KARIN M | |
| ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 12/21/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| _,· | | Application No. | Applicant(s) | | | |
|--|---|--|--|--|--|--|
| | | 10/057,352 | NGUYEN, HIEN VU | | | |
| | Office Action Summary | Examiner | Art Unit | | | |
| | | Karin M. Reichle | 3761 | | | |
| | The MAILING DATE of this communication ap | pears on the cover sheet with the c | correspondence address | | | |
| Period for | | | • | | | |
| WHIC - Exte after - If NO - Failu Any | ORTENED STATUTORY PERIOD FOR REPLICHEVER IS LONGER, FROM THE MAILING Densions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. Of period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tire I will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE | N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 31 M | May 2006. | | | | |
| 2a) <u></u> | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| 3)[| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposit | ion of Claims | | | | | |
| 4)⊠ | Claim(s) 1 and 2 is/are pending in the applica | ition. | • | | | |
| ٠,٣ | 4a) Of the above claim(s) <u>3-13</u> is/are withdrawn from consideration. | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | |
| 6)⊠ | 6)⊠ Claim(s) <u>1-2</u> is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8)[| Claim(s) are subject to restriction and/o | or election requirement. | | | | |
| Applicat | ion Papers | | | | | |
| | The specification is objected to by the Examin | er | | | | |
| • | The drawing(s) filed on is/are: a) acc | | Examiner. | | | |
| <i>,</i> — | Applicant may not request that any objection to the | • | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) | The oath or declaration is objected to by the E | examiner. Note the attached Office | Action or form PTO-152. | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| 12) | Acknowledgment is made of a claim for foreign | n priority under 35 U.S.C. § 119(a |)-(d) or (f). | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| | application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | • | | | |
| | | | • | | | |
| Attachmer | nt(s) | | | | | |
| 1) 🛭 Notic | ce of References Cited (PTO-892) | 4) Interview Summary | | | | |
| | ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) | Paper No(s)/Mail D 5) Notice of Informal F | | | | |
| | er No(s)/Mail Date | 6) Other: | The state of the s | | | |

DETAILED ACTION

1. Claims 10-13 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10-19-04.

2. Claims 3-9 are also now withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5-31-06.

Applicant's election with traverse of Group I in the reply filed on 5-31-06 is acknowledged. The traversal which is identical to that filed 10-19-04 is on the ground(s) that the claims of the groups are related and would not require different search and consideration of prior art. It is noted that the traverse does not set forth specifically how the Groups are related. This is not found persuasive because as set forth in restriction the Groups are unrelated and/or distinct. Group I does not require the specifics of the additional fibers or specific mass or specific density or specific diameter or specific GAT Absorbency as claimed in the Group II claims which serve as evidence claims and the Group II claims do not require a tampon, an absorbent structure consisting essentially of lyocell fibers, the specific density or the specific Syngyna Absorbency as claimed in the Group I claims which also serve as evidence claims. Furthermore the groups are not disclosed as capable of use together and claims 1 and 3 require mutually exclusive densities. Finally a serious burden would be present because, e.g., search and consideration for

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one of the inventions is necessary in a manner not likely to result in finding art pertinent to the other invention, i.e. differing fields of search, e.g. different search queries, e.g. Syngyna Absorbency for Group I as compared to GAT Absorbency for Group II, and Applicant has not rebutted such other than by conclusory statements unsupported by evidence.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The disclosure is objected to because of the following informalities: Is the structure of claims 3-10 and the abstract and that on page 5, lines 1-5 and Examples 5-6 one and the same? If so, note the density of the former, i.e. 4 grams per cubic centimeter, as compared to the latter, i.e. 0.4 grams per cubic centimeter. Should the densities be the same?

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written

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rejection. The language should focus on those factors reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in claim 1 the invention is an absorbent tampon comprising an absorbent structure consisting essentially of lyocell fibers.

Second, the terminology "consisting essentially of" is interpreted to limit the scope of the absorbent structure to the specified fibers and that which do not materially affect the basic and novel characteristics of such absorbent structure.

However and third, the instant application does not set forth what such "basic and novel characteristic(s)" to be so affected are considered to be, i.e. the application only discloses specific densities and absorbencies of <u>a tampon</u> of specific dimensions <u>consisting of lyocell</u> fibers not the "basic and novel characteristics" of an absorbent structure as claimed.

Finally, while pages 6-10 of the instant application set forth the composition of the absorbent structures, and thereby the tampons comprised thereof, as contemplated is not limited to only lyocell fibers but also combinations of such with other materials, both absorbent and non-absorbent, which materials have the capability of affecting characteristics of an absorbent structure, see, e.g. page 6, lines 19 et seq., it does not set forth the specifics of such combinations, i.e. what the exact compositions are, i.e. what the "basic and novel characteristics" of such combinations are and thereby, the absorbent structures composed thereof.

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of

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enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

5. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

See the discussion in the preceding paragraph. Since it is not clear what the basic and novel characteristics of the absorbent structure are, the claim language "absorbent structure consisting essentially of lyocell fibers" is unclear. See the Claim Language Interpretation section infra.

Claim Language Interpretation

6. Claim 1 sets forth an absorbent tampon having a specific density and a specific Syngyna Absorbency. It is noted while the Test is described generally on page 11, lines 19-24, the specifics of such test have not been set forth nor are such specifics readily available to the Examiner nor has a copy of such FDA regulation been provided to the Examiner. See the prior art rejection infra. Claim 1 further sets forth that the tampon comprises an absorbent structure consisting essentially of lyocell fibers. It is noted the tampon is not required to consist essentially of such fibers nor has the structure which does essentially consist of the fibers been defined as requiring more than at least two fibers. Furthermore, the terminology "consisting essentially of" is interpreted to limit the scope of the absorbent structure to the specified fibers and that which do not materially affect the basic and novel characteristics of such structure. However as set forth supra the instant application does not set forth what such "basic and novel

characteristic(s)" of the absorbent structure to be so affected are considered to be. Therefore if a structure including at least two lyocell fibers is absorbent it will be interpreted to read on the claim language.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodings et al PCT '133.

See '133 at abstract, the last paragraph of page 1, page 2 line 27-page 3, line 22, page 4, lines 20-32, page 5, second full paragraph, and thereby GB '637 at page 1, lines 103-110, '133 at page 7, lines 1-19 and page 9, i.e. '133 teaches an absorbent tampon comprising an absorbent structure "consisting essentially of "lyocell fibers, as best understood, see the Claim Language Interpretation section supra. The tampon has a density of about 0.3 to about 0.5 grams per cubic centimeter, i.e. about 0.35 and an absorbency of at least about 4.4 g/g as claimed in claim 1 and at least about 5g/g as claimed in claim 2, see Tables 1 and 3, e.g. No. 5 of Table 1. Applicant claims the absorbency is determined by the "well known Syngyna Test", see page 10, lines 15-18 and page 11, last paragraph, i.e. the absorbency is termed the "Syngya Absorbency". It is the Examiner's first position that since the '133 reference teaches at page 5, lines 24-25, and thereby

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GB '637 at page 1, lines 103-108, assessing the tampon absorbency also by the known Syngyna test, i.e. the absorbency is termed the "Syngina Absorbency" in '133 instead, that Tables 1 and 3 as discussed supra teach the claimed absorbencies. In any case, i.e. the Examiner's second position, since the tampon of '133 is made of an absorbent structure of lyocell fibers, as best understood, which fibers are processed as disclosed by the instant application, i.e. hydrothermally treated in a water bath of like temperature and time, and the tampon also has the claimed density, that there is sufficient factual evidence for one to conclude that such tampon would also inherently have the same absorbency when tested as disclosed by the instant application, if not already, i.e. have the same "Syngyna Absorbency".

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Conclusion

- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. It is further noted that '133 recognizes that higher temperatures and longer treatment necessitate a bath which contains less additives. The '668 reference also teaches processing of lyocell fibers.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karin M. Reichle Primary Examiner Art Unit 3761

KMR December 7, 2006